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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,359	09/25/2003	Luis A. Linares	3560-0132P	2652

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EXAMINER

GILBERT, SAMUEL G

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/26/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/669,359

Applicant(s)

LINARES ET AL.

Examiner

Samuel G. Gilbert

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 8 and 10-20 is/are rejected.
- 7) ☒ Claim(s) 4-6 and 9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/15/2003; 9/25/2003
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements filed 9/25/2003 and 12/15/2003 have been considered.

Drawings

The drawings are objected to because they appear to be informal drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "protective means" of claim 12 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The abstract of the disclosure is objected to because it should be no longer than 150 words and limited to a single paragraph. Correction is required. See MPEP § 608.01(b). Further, legal language such as "comprising" should not be used.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 - it is unclear how the third inflatable chamber is located equidistant between said tunnel channel (a single element).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 11, 13, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by D'Andrea (5,653,683).

Claim 1 - element 20 is a first inflatable chamber, element -10- is a supportive probe, inflation means -60-, radiation delivery means elements -23- or -24- and -50-.

Claim 2 - inflation balloon is accommodated around the distal end of probe -10-.

Claim 3 - the tubes -23- or sleeves -24- are fixed at the distal end as claimed.

Claim 11 - element -52- is in a catheter bore.

Claim 13 - rods -50- introduce the radioactive sources into the tunnel channels.

Claim 20 - in column 4 lines 48-53 the dose is specified and the treatment delivers the specified dose.

Claims 1-3, 13, 14, 15 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Winkler et al (6,482,142):

Claims 1-3, 13, 14, 15 and 20 - applicant's attention is invited to the embodiment of figure 3. Element -66- is a first inflatable member, element -12- is a supportive probe, elements -52- are radiation delivering means, elements -54-, -58- and -60- are hollow flexible tunnels, the examiner is taking expandable portions -66- and -68- as balloons, respective inflation ports similar to -26- would be required. In column 5, lines 5-10, it is set forth that the sources may be preloaded or connected to a wire -34- and used with an afterloader. It is the examiner's position that the sources -52- therefore may be connected to a wire and used with an afterloader as taught. To ensure proper source location the flexible tunnels must be connected to the inner balloon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8, 12, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Andrea (5,653,683).

Claim 7 - D'Andrea sets forth a device as claimed with radioactive delivery means on the outside of the first inflatable member as shown in figure 5 and indicates "FIG. 5 shows radiotherapeutic rods located on the exterior of the balloon, which can avoid the need for any discrete receiving members because the rods will be pushed outwardly by the expanding balloon." It is the examiner's position that this language does not preclude the use of sleeves -24- on the outside of the balloon. While one may use the device without sleeves -24- if one desired to maintain a specific radiation distribution, which is normally required in brachytherapy the user would use the sleeves -24- to insure the proper radial positioning of the rods -50- around the inflatable member. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to use sleeves -24- on the outside of the inflatable member to insure the proper radial positioning of the radiation in rods -50-.

Claim 8 - the spacing is shown to be equidistant in figures 4-6.

Claim 12 - figure 2, shows an unnumbered protective cap on catheter -52- but does not show protective caps on the remaining claimed elements. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to provide protective caps for all tubes entering the patients body before they are to be used to prevent matter foreign to the body from entering the body.

Claims 16-19 - the reference teaches a device as claimed including low dose rate and high dose rate, column 1 lines 53-58 but does not set forth the specific radiation source to be used. It is the examiner's position that all the modalities claimed by the applicant are old and well known in the brachytherapy arts. Therefore the examiner is taking official notice that such therapies are old and well known. In the absence of showing any criticality in the specific type of energy emitting source (shown by the fact that the applicant has claimed 4 different types of sources) the selection of any known source would have been an ordinary design expedient to one of ordinary skill in the art and of no patentable significance. D'Andrea states "The size, dose rate and spacing of these pellets is prescribed by the physician and assembled prior to and/or during the procedure in which the catheter device is ready for insertion through the body cavity orifice and into the body cavity."

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Andrea(5653,683) as applied to claims 1 and 13 above, and further in view of Winkler et al (6,482,142). D'Andrea teaches a device as claimed but does not set forth

the use of an afterloader even though a connection to catheter -52- is shown in Figure 2. Winkler et al teach that the sources can be preloaded or inserted on a wire with an afterloader, Column 5 lines 5-10. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to use the afterloader and source wire as taught by Winkler et al to load the sources taught by D'Andrea to reduce the risk of the attending medical staff to exposure from the radioactive sources as is well known in the medical arts.

Allowable Subject Matter

Claims 4-6 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 10 is would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

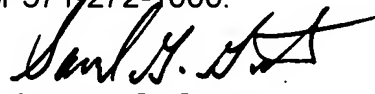
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 5,913,813; 5,863,285; and 6,409,652 teach related brachytherapy devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Samuel G. Gilbert
Primary Examiner
Art Unit 3735

sgg